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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,069	06/14/2001	Shubh D. Sharma	70025-US29743	1720

5179 7590 02/26/2003

PEACOCK MYERS AND ADAMS P C
P O BOX 26927
ALBUQUERQUE, NM 871256927

EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,069

Applicant(s)

SHARMA ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 12-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-11, species: peptide, S-thio-butyl, L or D-mercapto amino acid and Re(rhenium) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that invention IV is related to I as a process for making and the product so made. Both product and process, is argued, to require an S protected by an orthogonal S-protecting group. Applicants urge that they are not aware of a recombinant or fragment synthesis method resulting in the claimed product. This is not found persuasive because U.S. Patent 6,027,711 discloses said synthesis. Additionally, other synthetic methods are disclosed in said Patents including solution synthesis. The method further differs in the recitation of a formula for the library. The compound library does not recite for any formula. Hence, Group I has not been rejoined with Group IV.

Applicants admit that there is a difference between the libraries of group II and I. Group II, is argued, to include mimics of amino acid residues. It is also argued that the inventions are linked in design, operation and effect in its sequence of a metal-ion binding domain including a S-group. In response, the admitted difference is sufficient for the separate groupings of the distinct inventions. Peptidomimetics are peptide derivatives that contain a peptide backbone that is

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not amino acids. These peptidomimetics are designed differently from the non-derivatized peptides. A peptide can therefore be derivatized in numerous ways, especially in a library. Thus, a peptide derivatized in numerous way differs in design, operation and effect from a peptide.

Applicants argue that Invention III differs from Invention I in that Invention III is in solution. A library is solution does not require the additional component of a solid substrate of Invention I.

Applicants' election of species is noted. Applicants elected only the species recited in a claim of a specific group. Some of the groups do not recite a species in the claims. This does not mean that the groups do not contain the species. Page 5 of the last Office action recites the different genus claims encompassing the species. The species requirement applies to the entire genus encompassing said species, albeit, the species are only recited in some claims. The complete election of species made by applicants if groups IV and I are rejoined would be considered as applicable to the elected group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-3 and 12-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a

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nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1 and 4-11 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 4-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

The specification fails to describe a utility for the claimed library. The disclosure recites that the library is useful for screening. This is not a specific utility. All collection of compounds, as the instant library, is normally screened. Screening results in the desired compound that has a specific utility. "Congress intended that no patent be

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granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility....A patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. (Emphasis ours).

Claims 1 and 4-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well

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established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recited proviso "that the at least one amino acid residue containing at least one S-protected by an orthogonal S-protecting group is not the terminal amino acid at either the N or C terminus" is not described in the specification. There is no description of said proviso in the specification.

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Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is indefinite as combining different statutory subject matter. This claim contains a process step and a library product. For example, "synthesized on solid phase". "forming a metal ion-binding domains"; " ..solid phase synthesis and removable without cleaving the peptide.."; "cleavable bond attaching the sequence to solid phase" and "the orthogonal S-protecting group may be removed..." are method steps. These are not positive recitation of a component(s) present in a library. The components present in the library are confusing. It is not clear whether the library contains two separate components (a) and (b). That is, whether these components are two separate components of a library or one continuous peptide sequence linked to the metal binding domain. Furthermore, it is not clear whether the end product or component of the library containing the metal binding domain is solid bound. Cf. with page 28 of the disclosure. The term 'unique' within the claimed context is

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indefinite as to what constitutes said term. Also, the term "domain", within the claimed context, fails to set the metes and bounds of the claimed invention.

B). Claim 4 is confusing and does not further limit the compounds in the library. "N available for binding to a metal ion upon removal of the orthogonal S-protecting group", is a method step. It is suggested that applicants recite nitrogen for the single letter "N". This will eliminate ambiguity with N of the amino acid residue. It is also suggested that in claim 5, N or C terminus be amended to amino or carboxy terminus. This rejection has similar import to claim 7 and claim 10 both reciting process steps.

C). "The structural diversity" in claim 8 lacks antecedent basis of support from the base claim 1.

D). Claim 11 is indefinite as to the negative limitation of "including but not limited". The metes and bounds of this scope are unclear, especially in the absence of positive support in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of

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section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 4-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharma (U.S. 6,027,711).

Sharma discloses at col. 35, lines 20- 30 a library of the formula containing a Re binding cys peptide. Sharma further discloses at col. 37, line 5-30 that the library contain amino acid Cys which has a high affinity for metal complexing. The generalized view of the solid phase library of metallopeptides is shown at col. 37, lines 15-25. Accordingly, the broadly claimed library is fully met by the specific library of Sharma.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hnatowich et al (U.S. 5,980,861).

Hnatowich et al discloses at col. 15, line 15 up to col. 18, line 23 a library comprising of protein-nucleic acid (unique sequences as claimed), a chelator (a metal ion-binding domain

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including a S-protected group as claimed) and radionuclide. Libraries of chelators, nucleic acid-chelator compounds, and nucleic acid-chelator-radionuclides are useful for rapidly screening for compounds with desired properties, e.g., low non-specific binding, selected lipophilicity, high or low affinity for radionuclides. At col. 17, line 20, Hnatowich discloses the library of solid bound chelator including a S-protected group. Hnatowich discloses that chelators which bind to radionuclides are known in the art. Chelator moiety will be a tetradentate chelator, i.e., will be capable of four-point binding to a radionuclide. Also, an N2 chelator can chelate a radionuclide through two nitrogen atoms (e.g., amido nitrogens, e.g., of a peptide backbone) and two sulfur atoms (e.g., of a mercaptoacetyl moiety), while N3 chelators can chelate to a radionuclide through three nitrogen atoms and one sulfur atom. The chelator moieties include amidothiols, including, e.g., mercaptoacetyltripeptides, e.g., mercaptoacetyltriglycine, mercaptoacetyltriserine. Mercaptoacetyl-tripeptides can chelate radionuclides by coordination through the three amide nitrogens of the peptide backbone, and the terminal mercapto group. (See col. 10, line 66 up to col. 11, line 60). Hnatowich discloses at col. 2, lines 59-67 the radionuclides as selected from the group consisting of rhenium 186, rhenium 188 and rhenium 189. Hnatowich defines at col. 3, lines 14-65 the amino acid as an oligopeptide, e.g., mercaptoacetyl tripeptide, i.e., a

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tripeptide covalently linked (preferably at the amine terminus) to a mercaptoacetyl moiety, i.e., $--C(O)--CH_2-SR$, wherein R is hydrogen or a protecting group. The mercapto group is protected, preferably as a lower alkyl thioester, e.g., $--S--C(O)-\text{lower alkyl}$, prior to chelation with the radionuclide. Protecting groups for sulfur are known. The sulfur protecting group can be removed under mild conditions to unveil the free mercapto group, which can then participate in chelation of a radionuclide. The term "peptide" includes two or more amino acids covalently attached through a peptide bond. Amino acids, which can be used in peptide molecules, include those naturally occurring amino acids found in proteins such as cysteine, arginine, proline, histidine, phenylalanine, tyrosine, and tryptophan. The term "lower alkyl" refers to an alkyl group having from 1 to 6 carbon atoms. Exemplary lower alkyl groups include methyl, ethyl, n-propyl, isopropyl, n-butyl, isobutyl, sec-butyl, tert-butyl, n-pentyl, and n-hexyl.

Hnatowich discloses all of the claimed features except that the peptide sequence employed by Hnatowich is PNA i.e., peptide-nucleic acid. The claims recite comprising that does not preclude the presence of nucleic acid. Hnatowich, like the claimed invention, discloses the binding domain (chelator) as a peptide sequence including a S-protected group. The claimed invention would have been obvious to one having ordinary skill

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in the art at the time the invention was made. All the features of the claimed are disclosed or at least suggested by Hnatowich.

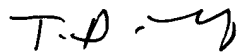
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
February 21, 2003